

INTERVIEW SUMMARY

Applicant thanks Examiner Q. Janice Li for the courtesy of the telephonic interview, held November 14, 2006 between the Examiner and Applicant's representatives, Lawrence S. Graham and Nikolaos C. George (collectively, "Applicant's representatives"). Applicant's representatives discussed the pending non-final Office Action with the Examiner. The Examiner indicated that amending claim 24 to recite the limitations of claim 29 would obviate all of the pending rejections, including the rejections under 35 U.S.C. § 112, first paragraph. Applicant's representatives agreed to so amend the claims, and to amend the claims to specify that the recited placental stem cells comprise CD34⁻ stem cells. With respect to the composition claims, the Examiner indicated that an additional search of the art would be performed, though Applicant's representatives pointed out that prior searches would have revealed any art identifiable in a new search. Applicant's representatives agreed to file a formal response to the pending Office Action.

REMARKS

Claims 24-50 are currently pending in the application. Claims 29 and 46-50 are canceled herein without prejudice. Claim 24 is amended to specify that the placental stem cells recited therein comprise CD34⁻ stem cells that are OCT-4⁺, SSEA3⁻ or SSEA4⁻. Support for the amendment to claim 24 is found in claim 29, and in the specification at least at pages 4 and 28. Claim 30 is amended to depend from claim 24, and to conform dependency to claim 24. Claim 31 is amended to specify that the method comprises seeding CD34⁺ stem cells onto the recited tissue matrix. Support for the amendment to claim 31 is found in the specification at least at page 3, lines 21 to page 4, line 11, and page 28. Claims 41-45 are amended to correctly depend from claims 25, 27, 28, 24 and 26, respectively. New claims 51-57 are added. Support for new claims 51-57 is found in the specification at least at page 3, lines 21 to page 4, line 11, and page 28. No new matter is thus introduced by these amendments.

Attorney Docket Number

The Office Action cover sheet indicates that the Attorney Docket Number is 011307. Please amend the Attorney Docket Number for this application to 9516-101-999.

The Rejections Under 35 U.S.C. § 112, First Paragraph Should Be Withdrawn

Claims 24-50 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Office Action at pages 2-3.

As noted above, the Examiner has indicated that the claims would be allowable if they incorporate the limitations of claim 29. *See* Office Action, page 9; Interview Summary, mailed November 1, 2006. Applicants have so amended the claims.

It is noted that the Examiner first states that “[t]he Declaration [of Dr. Yi, filed August 3, 2006] mentioned seven figures, but only figures 4 and 6 are on record currently.” Office Action at page 3. However, Applicant appreciates and acknowledges the Examiner’s statement that the Declaration of Dr. Ye appears to be sufficiently persuasive to address the rejections of record, though it was deemed to be incomplete. Office Action at page 3. It is also noted that the Examiner, subsequent to the mailing date of the present Office Action, informed Applicant’s representatives that the missing figures had been located and considered. *See* Examiner Interview Summary, mailed November 1, 2006.

In making the rejection, the Examiner contends that Huss, *J. Hematother. & Stem Cell Res.* 9:783-793 (2000) (“Huss”) “provides evidence contrary to Dr. Ye’s assertion on the distinction of placental CD34⁻ stem cells and CD34⁻ mesenchymal stem cells because a

totipotent stem cell should be able to generate embryoid or embryoid-like bodies.” Office Action at page 3. Applicant notes that Huss never states or suggests that the stem cells discussed therein produce embryoid bodies or embryoid-like bodies. Thus, there is no evidence on record that the stem cells discussed in Huss actually do or can form embryoid or embryoid-like bodies. Moreover, Huss itself only speculates as to the CD34⁻ mesenchymal stem cells’ potency; the reference fails to disclose any *proof* that such stem cells have the capacity to “generate whole organ systems”. Thus, Huss is not evidence that one of skill in the art would not recognize that Applicant has adequately described the recited placental stem cells. As such, Huss does not evidence any lack of written description of the claims as amended.

For the above reasons, Applicant respectfully requests that the Examiner withdraw this rejection of the claims.

The Rejections Under 35 U.S.C. § 112, Second Paragraph Should Be Withdrawn

Claims 24-31 and 35-50 are rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. Office Action at page 3. At the outset, Applicant notes that claims 29 and 46-50 have been canceled without prejudice.

Specifically, the Examiner contends that the term “flush” in claim 24 is indefinite in that “[t]he specification fails to define the condition for ‘flush’, it is unclear what step(s) are encompassed by ‘flush’, and thus the metes and bounds of the claims are uncertain.” *Id.* Without conceding the propriety of the Examiner’s rejection, and solely to further prosecution of the claims, Applicant has amended claim 24 to specify that the recited placenta is *perfused* to remove residual blood. By merely substituting these two interchangeable terms, this amendment does not change the scope of the claims. As amended, claim 24 is definite, as are the remaining rejected claims, each of which ultimately depends from claim 24. Applicant respectfully requests that the Examiner withdraw this basis of rejection.

The Rejections Under 35 U.S.C. § 102 Should Be Withdrawn

The Examiner has rejected claims 24-27, 31, 35, 36, 41 and 42 under 35 U.S.C. 102(e) as allegedly anticipated by Pykett *et al.*, U.S. Patent No. 6,548,299 (“Pykett”). Office Action at pages 4-5. As noted above, the Examiner has indicated that the claims would be allowable if they incorporate the limitations of claim 29. *See* Office Action, page 9; Interview Summary. Applicants have so amended the claims.

For a reference to anticipate, the reference must disclose each and every limitation of the claim to which it is compared. *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d

1304 (Fed. Cir. 2002); *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292 (Fed. Cir. 2002).

Without conceding the propriety of the Examiner's rejection, and solely to facilitate prosecution of the claims, Applicant has amended claim 24 to specify that the method comprises seeding a tissue matrix with placental stem cells that comprise CD34⁻ stem cells that are SSEA3⁻, SSEA4⁻, or OCT4⁺. Pykett does not disclose cells that are CD34⁻ that are CD34⁻ and either SSEA3⁻, SSEA4⁻, and/or OCT4⁺, or matrices comprising such cells. Indeed, Pykett only discloses the use of hematopoietic stem cells. As such, Pykett only discloses the use of stem cells that are CD34⁺. Thus, Pykett does not anticipate claim 24 as amended. Because Pykett does not anticipate claim 24, the reference does not anticipate any of claims 25-27 and 31-36, each of which ultimately depends from claim 24. Applicant therefore respectfully requests that the Examiner withdraw the rejection of the claims on this basis.

The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

The Examiner has rejected claims 24, 26-28, and 35-40 as obvious over Pykett in view of Goldstein *et al.* (U.S. Patent No. 5,899,936; "Goldstein") and Atala (U.S. Patent No. 6,753,181; "Atala"). Office Action at pages 5-6. The Examiner cites Pykett for the disclosure that formed the basis of the 102(e) rejection, above. The Examiner cites Goldstein and Atala for teaching ratios of fibronectin to heparin for coating bioprostheses, and a process of decellularization of a natural tissue for making an implant. Office Action at page 5.

Obviousness under 35 U.S.C. § 103(a) requires a determination that the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The combination of cited references must teach each and every limitation of the rejected claims. See M.P.E.P. 2143.03. If an independent claim is nonobvious, then every claim depending therefrom is also nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

As noted above, Applicant has amended claim 24 to specify that the recited placental stem cells comprise CD34⁻ stem cells that are SSEA3⁻, SSEA4⁻, and/or OCT4⁺. Pykett does not disclose a method of making a tissue matrix using placental stem cells that are that are CD34⁻ and either SSEA3⁻, SSEA4⁻, and/or OCT4⁺, as specified by claim 24. Neither Goldstein nor Atala supply the teaching or suggestion, missing in Pykett, of seeding a tissue matrix with such stem cells. The combination of Pykett, Goldstein and Atala, therefore, does not teach or suggest all of the limitations of the claim 24, and cannot render claim 24

obvious. Because claim 24 is not obvious over the cited references, claims depending from claim 24 are nonobvious, as well. *In re Fine*, 837 F.2d at 1071.

Applicant therefore respectfully requests that the Examiner withdraw this rejection of the claims.

The Rejection Under 35 U.S.C. 102/103 Should Be Withdrawn

The Examiner has rejected claims 41-50 under 35 U.S.C. 102(e) as anticipated by, or under 35 U.S.C. 103 as obvious over, Anderson *et al.* (U.S. Patent No. 6,328,762; “Anderson”) as evidenced by Huss. Office Action at pages 6-8. At the outset, Applicant notes that claims 46-50 have been canceled without prejudice.

The Examiner contends that Anderson teaches a tissue matrix (that is, a porous prosthetic implant) seeded with, *e.g.*, stem cells from bone marrow or mesenchymal stem cells. Office Action at page 6. The Examiner further contends that Huss teaches that “CD34⁻ bone marrow cells contains [*sic*] a population of stem cells that are totipotent.” Office Action at page 6.

As noted above, Applicant has amended claim 24 to specify that the recited placental stem cells comprise CD34⁻ stem cells that are SSEA3⁻, SSEA4⁻, and/or OCT4⁺. The tissue matrices specified by each of claims 41-50 are made by the method of claim 24, or claims depending from claim 24, and thus comprise placental stem cells that are CD34⁻ and SSEA3⁻, SSEA4⁻, and/or OCT4⁺. Anderson does not disclose a tissue matrix comprising placental stem cells that are that are CD34⁻ and SSEA3⁻, SSEA4⁻, or OCT4⁺. The Declaration of Dr. Ye, filed August 3, 2006, paragraph 22, explains that stem cells from bone marrow or mesenchymal stem cells are different from placental stem cells. As explained above, Huss fails to teach placental stem cells, and thus fails to supply the teaching or suggestion, missing in Anderson, of placental stem cells that are SSEA3⁻, SSEA4⁻, and/or OCT4⁺. As such, Anderson alone, and the combination of Anderson and Huss, fail to teach or suggest tissue matrices comprising placental stem cells that are CD34⁻ and SSEA3⁻, SSEA4⁻, and/or OCT4⁺. Because neither Anderson alone, nor the combination of Anderson and Huss teach or suggest all of the limitations of the rejected claims, the cited references cannot render claims 41-45 obvious.

For the above reasons, Applicant respectfully requests that the Examiner withdraw this rejection of claims 41-45.

The Objections to the Claims Should Be Removed

The Examiner states that “[c]laims 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form . . .”. Office Action at page 9. Claim 30 depends from claim 29. Applicant has amended claim 24 to include the limitations of claim 29. Thus, claim 24, as amended, should be allowable. As the rejections of the remaining claims, which ultimately depend from claim 24, do not rest on the specific limitations of those claims, claims depending from claim 24 are also allowable. Applicant therefore respectfully requests that the Examiner withdraw this objection to the claims.

CONCLUSION

Applicant respectfully requests that the above remarks and accompanying documents be entered in the present application file. An early allowance of the present application is respectfully requested. No fee is believed due in connection with this Amendment. However, if any fee is deemed to be due, please charge such fee to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date: December 14, 2006


for: Lawrence S. Graham Reg. No. 49,020
Anthony M. Insogna Reg. No. 35,203

JONES DAY
222 East 41st Street
New York, NY 10017
(212) 326-3939